IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL TECHNOLOGIES, INC., *Plaintiff,* *v.* KURIN, INC., *Defendant.*	Civil Action No. 1:19-cv-00097-CFC **JURY TRIAL DEMANDED** **Redacted Version**

DEFENDANT KURIN, INC.'S CONCISE STATEMENT OF FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT (NO. 1) OF INVALIDITY OF U.S. PATENT NO. 9,855,001 DUE TO INDEFINITENESS

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Kurin submits the following concise statement of undisputed facts in support of its Motion for Summary Judgment (No. 1) of Invalidity of U.S. Patent No. 9,844,001 Due to Indefiniteness:

1. Claim 1 of the #001 patent recites, in part, a "diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet, the diverter configured to transition from the first operating mode to the second operating mode as a result of the initial volume of bodily fluid flowing from the patient and substantial pressure equalization[.]" Declaration of Jacob Zweig in Support of Defendant Kurin, Inc.'s Motion for Summary Judgment (No. 1) of Invalidity of U.S. Patent No. 9,855,001 Due to Indefiniteness ("Zweig Dec1."), Ex. A, claim 1.

2. Claim 21 of the #001 patent recites, in part, a "diverter defining a first fluid flow path that allows the initial volume of bodily fluid to flow from the patient until pressure substantially equalizes, and a second fluid flow path that allows a subsequent volume of bodily fluid to flow from the inlet to the outlet after the initial volume of bodily fluid has been sequestered, the diverter configured to divert the flow of bodily fluid to the second fluid flow path as a result of receiving

the initial volume of bodily fluid from the patient and substantial pressure equalization[.]" Zweig Decl., Ex. A, claim 21.

3. Claims 1 and 21 of the #001 patent do not state at what locations pressures must be substantially equal or substantially equalize. Zweig Decl., Ex. A, claims 1 & 21; Ex. B, 150:2-7 ("Q. ... What pressures must be substantially equalized? ... THE WITNESS [Magnolia's expert, Dr. Santiago]: So as I understand the claim the specific pressures are not called out in the claim ....").

4. The only recitations of "pressure" or "pressures" that "equalizes" or "equalize" in the written description of the #001 patent are at 5:35-44, 5:65-67, and 6:23-27. Zweig Decl., Ex. A, 5:35-44; 5:65-67; 6:23-27.

5. Dr. Santiago opined that, in the #001 patent, "one way of diverting an initial blood volume is through use of a single blood flow path." Zweig Decl., Ex. C, ¶¶ 121-122.

6. The passages of the written description at 5:35-44, 5:65-67, and 6:23-27 referencing pressure equalization relate specifically to what Dr. Santiago refers to as "single blood flow path" embodiments. Zweig Decl., Ex. A, 5:35-44; 5:65-67; 6:23-27; Figs. 1, 3A-B, 4A-B; Ex. C, ¶¶ 121-122.

7. Dr. Santiago opined that, in the #001 patent, "[a]nother way of diverting an initial blood volume, as shown in Figures 6A/6B, utilizes a flow path

from the patient that branches into two separate paths." Zweig Decl., Ex. C, ¶¶ 123-124.

8. This Court construed "diverter" as means-plus-function, with the function "to divert (or direct) fluid flow from one fluid flow path to a second fluid flow path" and the structure "an inlet, at least two outlets, and either a switchable valve or flow control blocks." (D.I. 75, at p. 2.)

9. The claimed "diverter" corresponds to the "diversion mechanism" embodiments. Zweig Decl., Ex. A, 6:60-9:15, Figs. 5, 6A-B, 7A-B; Ex. C, ¶¶ 123-124; (D.I. 75, at p. 2.)

10. The only pressure equalization discussed in the specification of the #001 patent is in connection with "single blood flow path" embodiments that do not include the claimed "diverter." Zweig Decl., Ex. A, 5:35-44; 5:65-67; 6:23-27; Figs. 1, 3A-B, 4A-B; Ex. C, ¶¶ 121-124; (D.I. 75, at p. 2.)

11. The only reference to locations at which pressures equalize in the specification of #001 patent is as follows: "Once the pressures equalize between the lumen of the first needle 108 and the lumen of the second needle 110, the blood tends to stop flowing from the vein 202 to the pre-sample reservoir 104." Zweig Decl., Ex. A, 5:41-44; Ex. C, ¶ 121.

12. Claim 1 of the #001 patent does not recite a "needle." Zweig Decl., Ex. A, claim 1.

13. Claim 21 of the #001 patent recites only one "needle." Zweig Decl., Ex. A, claim 21.

14. The prosecution history of the #001 patent provides no guidance as to where there must be "substantial pressure equalization" in claims 1 and 21. Zweig Decl., Ex. D, ¶¶ 1154-1162 (referencing "prosecution history" in discussion of "substantial pressure equalization" for claim 1 only in ¶ 1157); 1194 (referring back to claim 1 discussion of "substantial pressure equalization" for claim 21).

15. Dr. Santiago references the "prosecution history" but does not cite to it in connection with "substantial pressure equalization" or support in any way his assertion that it would aid in understanding the scope of this claim term. Zweig Decl., Ex. D, ¶ 1157.

16. Dr. Santiago testified, "Q. ... [P]ressure is measured at a place, right? A. Absolute pressure is pressure differences that were measured over two places. Q. Okay. And so if we're talking about equalization, we're talking about two different pressures, correct? Two different places where pressure should be known. A. At least two." Zweig Decl., Ex. B, 150:11-19.

17. Dr. Santiago testified that, to evaluate compliance with the "substantial pressure equalization" requirement, "when there's liquid in both points, a continuous or contiguous volume of liquid between those two points,

when you look at those two points and compare their pressure it would meet the limitation." Zweig Decl., Ex. B, 160:19-161:3.

18. Dr. Santiago testified, "Q. … [the] specification also doesn't identify where pressure should be equalized, does it? … THE WITNESS: The spec does not point to two points to measure pressures." Zweig Decl., Ex. B, 151:19-152:2.

19. Dr. Santiago's deposition testimony did not identify two locations where pressures must be compared to determine whether "substantial pressure equalization" has occurred "to evaluate claim 1." Zweig Decl., Ex. B, 156:6-14 ("Q. … I would like to understand your opinion as to where substantial pressure equalization must be determined to evaluate claim 1. … THE WITNESS: ... [O]ne reasonable place to look is in a diverter or in components that are fluidically coupled to the diverter.").

20. When asked whether the claimed "substantial pressure equalization" is "a process of equalization" or "a state where some pressures are substantially equal," Dr. Santiago's answer did not say which he believed to be required; he testified instead that "as the liquid flow rate in the U tube slows down, there's a simultaneous substantial pressure equalization" and then "a state of substantial pressure equalization" and then "a state of fairly complete pressure equalization." Zweig Decl., Ex. B, at 147:23-148:16; *see also id.* at 145:21-147:22; 161:4-164:6.

21. Dr. Santiago's infringement expert report states that there is "substantial equalization of liquid pressures within the U-shaped diversion chamber" of the Kurin Lock. Zweig Decl., Ex. C, ¶ 59; *see also* ¶ 179.

22. Dr. Santiago's infringement expert report features an annotated photo identifying certain features of the Kurin Lock at ¶ 50. Zweig Decl., Ex. C, ¶ 50.

23. Dr. Santiago's infringement expert report states that "[a]s the initial volume of blood fills the U-shaped side channel and the porous plug seals, the pressure from the blood in the U-shaped side channel equalizes with the patient's blood pressure, which causes the second mode of operation where the blood is directed down the sample channel" in the Kurin Lock. Zweig Decl., Ex. C, ¶ 180.

24. Dr. Santiago's infringement expert report states that there is "substantial pressure equalization between the inlet and the U-shaped diversion chamber" in the Kurin Lock. Zweig Decl., Ex. C, ¶ 219.

25. Dr. Santiago's rebuttal expert report states that "substantial pressure equalization" occurs "in the Kurin Lock device relative to the pressure in the patient's vein." Zweig Decl., Ex. D, ¶ 1158.

26. Dr. Santiago testified that substantial pressure equalization in the Kurin Lock could occur between "[t]wo points within the U tube structure," Zweig Decl., Ex. B, 150:24-151:7, but that this is just "one example," *id.* at 158:6-21.

27. Dr. Santiago testified that substantial pressure equalization in the Kurin Lock could occur between "say, halfway between the 180-degree turn and the dual valve assembly" and "another point in the same horizontal line in the center of the U tube channel on the far side of the 180-degree turn." Zweig Decl., Ex. B, at 159:17-160:3.

28. Dr. Santiago testified that substantial pressure equalization in the Kurin Lock could occur at "[t]wo other points within the U structure." Zweig Decl., Ex. B, at 164:8-17.

29. Dr. Santiago testified that "you could look at other locations" to determine substantial pressure equalization including points outside the U structure such as the "inlet." Zweig Decl., Ex. B, at 165:15-166:15.

30. Dr. Santiago testified, "Q. … [A]re there any locations within the Kurin Lock that you could compare pressure, and if you found substantially equal pressure, it wouldn't satisfy this claim? … THE WITNESS: … [T]here's within the plastic. There's points between the porous plug and the U structure. There's pressures within the porous plug. It's a complex question. I'm not ready to exclude any other points." Zweig Decl., Ex. B, at 166:20-167:7.

31. In discussing how to evaluate compliance with the "substantial pressure equalization" requirement, Dr. Santiago testified "as the liquid flow rate decreases, there's a process wherein the two pressures get closer to each other, so

the pressure difference decreases. And when the liquid comes to a rest, barring any effects of gravity, the two pressures at those two locations will be substantially equal." Zweig Decl., Ex. B, 160:19-161:12.

32. Dr. Santiago's infringement expert report states that, at various times and in various locations during operation of the Kurin Lock, pressures increase, decrease, and equalize, including that "pressure differences within the liquid volume of the reservoir region (e.g. the U-shaped channel sections) progressively decrease …[,]" "pressure in the liquid in the Y-junction progressively increases," "[a]t some point, … pressure equalization within the U-shaped diversion chamber" occurs or is occurring, and "[a]ssuming a negligible air-to-liquid capillary pressure difference and assuming negligible hydrostatic pressure difference between the venal pressure and the liquid in the Kurin Lock, the pressure of both the air and liquid in the Kurin Lock eventually equalize to the venal pressure." Zweig Decl., Ex. C, ¶¶ 58-60.

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CERTIFICATION BY COUNSEL

The foregoing document complies with the type-volume limitation of the parties' Scheduling Order, D.I. 24, dated June 20, 2019 and this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes was prepared in Times New Roman, 14-point. According to the word processing system used to prepare it, the brief contains 1,731 words, excluding the case caption, signature block, table of contents and table of authorities.

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CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on May 27, 2021, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed.

I further certify that on the same date the attached document was electronically mailed to the following person(s):

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